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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 10/511,484 | 10/21/2005 | Henry Nicolas Jabbour | 20747/200 | 4407 |

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07/31/2007

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| EXAMINER |
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LUKTON, DAVID

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| ART UNIT | PAPER NUMBER |
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1654

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| MAIL DATE | DELIVERY MODE |
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07/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/511,484

Applicant(s)

JABBOUR ET AL.

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 10-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-9 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

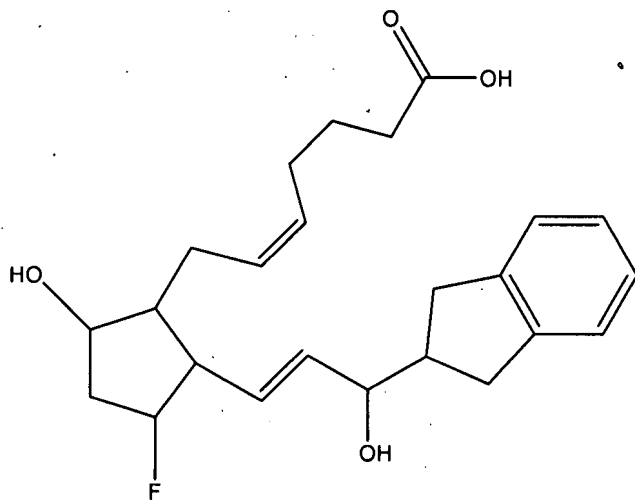
Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claims 1-29 remain pending.

Applicants' election of Group I (claims 1-9) is acknowledged. Applicants have argued that the examiner would derive no benefit by limiting his search burden. However, this is not true; examination of all the claims would indeed impose an "undue burden".

Applicants' election of AL 8810 is acknowledged. As stated on page 7, the chemical name for this is (5Z, 13E) - (9S, 11S, 15R) - 9, 15-dihydroxy-11-fluoro-15-(2-indanyl)- 16, 17, 18, 19, 20-pentanoic acid, which has the following structure (stereochemistry excluded):



Claims 10-20 are withdrawn from consideration.

Claims 1-9 are now subject to further restriction/election as set forth below.



The following abbreviations are used hereinbelow:

APFR: an agent that prevents $\text{PGF}_{2\alpha}$ from having its effect on the FP receptor;

IPAE: an inhibitor of PGES and/or an antagonist of EP2 or EP4;

PGES: prostaglandin E synthase;

The following subgenera are now defined:

G1: an inhibitor of PGES is administered;

G2: an antagonist of EP2 is administered;

G3: an antagonist of EP4 is administered

.

Restriction to one of the following inventions is required under 35 U.S.C. §121 (the numbering begins with "6" to avoid conflict with the previous numbering system):

6) Claims 1-7, drawn to a method of treating (or preventing) menorrhagia, wherein there is no requirement or suggestion that an IPAE be administered.

7) Claims 8-9, drawn to drawn to a method of treating (or preventing) menorrhagia, wherein there is a mandate to administer an IPAE.

The inventions are distinct.

Inventions 7 and are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations. (M.P.E.P. § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because. The subcombination has separate utility; the APFR can be administered without the IPAE. Nevertheless, in the event that Group 6 is elected, and claims therein found allowable, it is more likely than not that novelty would accrue to Group 7. Accordingly, in the event that Group 6 is elected, and claims therein found allowable, the restriction between Group 6 and Group 7 will have to be revisited.



Applicants are required under 35 U.S.C. §121 to elect disclosed species (as follows) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that Group 6 is chosen for initial examination, election of each of the following is required:

- a) one of the following: (i) in the elected method, the AL 8810 is to be administered by itself, without a carrier or (ii) in the elected method, the AL 8810 is to be administered

in combination with a carrier;

b) in the event that the AL 8810 is administered in combination with a carrier, election is required of a specific and fully defined carrier;

e) the route of administration of the AL 8810 (or composition containing the AL 8810).

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In the event that Group 7 is chosen for initial examination, election of each of the following is required:

a) one of the following: (i) AL 8810 and G1 are administered; (ii) AL 8810 and G2 are administered; (iii) AL 8810 and G3 are administered; (iv) a combination of AL 8810, G1 and G2 are administered; (v) a combination of AL 8810, G1 and G3 are administered; (vi) a combination of AL 8810, G2 and G3 are administered; (vii) a combination of AL 8810, G1, G2 and G3 are administered;

b) election is required of a specific G1, G2 and/or G3 that is consistent with (a) above;

c) one of the following: (i) AL 8810 is administered concomitantly with G1, G2 and/or G3, or (ii) AL-8810 and G1/G2/G3 are administered sequentially;

c) one of the following: (i) the AL-8810 and G1/G2/G3 are administered as such, without a carrier, or (ii) the AL-8810 and G1/G2/G3 are administered in combination with a carrier;

d) in the event that the AL-8810 and G1/G2/G3 are administered in combination with a carrier, election is required of a specific carrier;

e) the route of administration of the AL 8810 and G1/G2/G3.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added

after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read 'D. Lukton', is positioned above the printed name.

DAVID LUKTON, PH.D.
PRIMARY EXAMINER